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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,426	08/12/2003	Samuel J. Epstein	12013/47601	5077

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

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11/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/638,426	Applicant(s) EPSTEIN ET AL.	
	Examiner Christopher D. Koharski	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-21 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8-18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the RCE filed 9/10/2007 in which claims 1 and 19 were amended. Currently claims 1-5 and 8-21 are pending for examination with claims 4-5, 8-18 and 21 withdrawn from a previous election restriction.

Claim Objections

Claims 1 and 20 are objected to because of the following informalities: Regarding claim 1, the preamble and body of the claim mention "shear thickening or Bingham fluids" while later in the claim "the non-Newtonian fluid" is recited, this is improper because it lack antecedent basis, because the description of the non-Newtonian fluid is broader than the "shear thickening or Bingham fluids", i.e. non-Newtonian fluids can encompass shear-thinning fluids also or any fluid in which the viscosity changes with an applied strain rate. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims a channel containing a Bingham fluid, Examiner regards this term as indefinite, (see NPL "Bingham Fluid"), a Bingham fluid is an idealized model of fluid characteristics and does not exist and is a mathematical modeling formula (see also MPEP 2105).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Zarate (5,662,619). Zarate discloses a venous dialysis needle.

Regarding claims 1-3 and 19-20, Zarate discloses a device and method for direct delivery of a shear thickening of a Bingham fluid (blood, see NPL, Blood Rheology and Introduction to Biomedical Engineering) having therapeutic properties, the device comprising: a channel (12) having a proximal (near 16) and distal end (15) with a lumen extending therethrough, the channel containing a shear thickening or Bingham fluid (blood), the channel configured to expose the fluid to a viscosity adjuster comprising protrusions (26, 28, 30) which form a constricted flow orifice (near 14, 20) (Figures 1-13) and causes an increase in the viscosity of the fluid.

Claim Rejections - 35 USC § 102

Claims 1-3 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan (6,409,972). Chan discloses prepackaged liquid bone cement.

Regarding claims 1-3 and 19-20, Chan discloses a device and method for direct delivery of a shear thickening of a Bingham fluid (polymerizing bone cement) having therapeutic properties, the device comprising: a channel (95) having a proximal (near 95) and distal end (near 66) with a lumen extending therethrough, the channel

containing a shear thickening or Bingham fluid (bone cement), the channel configured to expose the fluid to a viscosity adjuster comprising protrusions (71, 72) which form a constricted flow orifice (near 66) (Figures 4, 6 and 10) and causes an increase in the viscosity of the fluid.

Claim Rejections - 35 USC § 102

Claims 1-3 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Antanavich et al. (6,132,396). Antanavich et al. discloses an apparatus for applying tissue sealant.

Regarding claims 1-3 and 19-20, Antanavich et al. discloses a device and method for direct delivery of a shear thickening of a Bingham fluid (fibrin composition) having therapeutic properties, the device comprising: a channel (near 24) having a proximal (near 22,23) and distal end (25) with a lumen extending therethrough, the channel containing a shear thickening or Bingham fluid (fibrin composition), the channel configured to expose the fluid to a viscosity adjuster comprising protrusions (26, 29) which form a constricted flow orifice (near 25) (Figure 4) and causes an increase in the viscosity of the fluid.

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 19-20 have been considered but are moot in view of the new ground(s) of rejection.

As per Applicant's previous request, Examiner herein includes and cites relevant NPL literature that discloses that blood is a well-known non-Newtonian, Bingham fluid

and background exceeding Applicant's specification of the properties/models of a Bingham fluid.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

11/16/07



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